FDA Preliminary Public Health Notification*: Vail Products Enclosed Bed Systems

Updated: June 24, 2005

Original date: March 25, 2005

Vail Products, Inc. of Toledo, Ohio, publicly stated on June 16, 2005, that it is permanently ceasing the manufacture, sale and distribution of all Vail enclosed bed systems. Vail Products will no longer be available to provide accessories, replacement parts, or retrofit kits. On June 23 and 24, 2005, revised instruction manuals and warning labels were mailed to customers with Vail 500, Vail 1000 or Vail 2000 enclosed bed systems. The revised manuals include new warnings, precautions, and instructions for use.

Recommendations for Users of Vail Enclosed Bed Systems

Use of the Vail bed poses a public health risk because patients can become entrapped and suffocate, resulting in severe neurological damage or death. For this reason, FDA is advising hospitals, nursing homes and consumers who have a Vail enclosed bed system to **stop using it and move the patient to an alternate bed**. Consumers who are using Vail beds at home can consult with their physicians about other options.

If continued use of the Vail bed is the only option, the following safety precautions recommended by Vail should be followed:

- **Use these beds only for patients who are at least 45 inches tall and who weigh at least 46 lbs**. Do not use the beds for patients smaller than this.

- **Do not use these beds for patients who exhibit burrowing behavior**; who are violent, aggressive, combative, or suicidal; who have multiple lines; or who have excessive PICA eating disorder.

- **Use only the mattress recommended by the manufacturer** to reduce the possibility of entrapment between the bed rails and the mattress**.**

- **Always leave the side rails in the "Up" and locked position,** except when you are providing patient care or moving the patient from the bed.

- **Always return the bed to the flat position** while the patient is unattended, unless head elevation has been ordered by a physician.

- **Keep all canopy sides zipped and locked at all times**. Never leave a patient unattended while the cover is unzipped.

Additional recommendations for the Vail 1000 and 2000 models:

- **Never leave the Hi-Lo feature in the high position while the patient is unattended.** The Hi-Lo feature allows the entire bed sleep surface to be raised and lowered. When the bed is in the "Hi" position, the risk of entrapment is increased.

- **If you have received a retrofit kit, make sure it is properly installed**. Although the retrofit kit is intended to reduce the risk of entrapment, its effectiveness was never validated by the manufacturer. The FDA has no assurance that the retrofit kits will adequately reduce the risk of entrapment and is aware of at least 4 entrapments, including 2 deaths, that occurred with the kit installed.

Facilities that have engineers available should check the beds for possible entrapment zones in all possible bed positions. Entrapment zones can include, but are not limited to, areas between the side rails and mattress, between the mattress and canopy in places where the rails do not extend, and areas between the end rails and mattress.

If you did not receive the revised labeling sent by Vail, you should contact Vail as soon as possible at 1-800-235-8245 to receive the materials.

Background Information

Vail enclosed bed systems are canopy-like padded beds covered with nylon netting that is zipped into place. They are used for at risk patients, both adults and children, with cognitive impairment, unpredictable behavior, spasms, seizures, and other disorders. The beds are used as an alternative to a physical or drug restraint to reduce falls from a bed and prevent patients from wandering.

On March 22, 2005, in response to ongoing concerns about manufacturing quality and labeling, the FDA and the U.S. Department of Justice initiated a seizure of all Vail model 500, 1000, and 2000 enclosed bed systems present at Vail's facility at that time.

Approximately 5,000 of these beds were distributed nationwide. FDA is aware of approximately 30 adverse event reports, including at least 8 deaths, resulting from entrapments, falls, and other incidents. More than half of the 30 incidents involved children 16 and under.

The Vail 500, 1000, and 2000 beds can be identified by a Vail label containing a model number. The label is on the front of the bed or on one of the legs.

Reporting Adverse Events to FDA

FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect that a reportable adverse event was related to the use of a Vail enclosed bed system, you should follow the reporting procedure established by your facility.

We also encourage you to report adverse events related to Vail enclosed bed systems that do not meet the requirements for mandatory reporting. You can report these directly to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787; or online at http://www.fda.gov/medwatch/report.htm. Consumers can also report directly to MedWatch.

Getting More Information

For further details on the seizure, see FDA's 3/22/05 Talk Paper at: www.fda.gov/bbs/topics/ANSWERS/2005/ANS01347.html.

For questions regarding the information in this notification, contact Vail Products, Inc., Customer Service Dept. at 1-800-235-8245 or visit the firm's website at http://www.vailbed.com.

If you have questions for FDA, please contact the Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, Fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov. You may also leave a voice mail message at 301-594-0650 and we will return your call as soon as possible.

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Sincerely yours,

Daniel G. Schultz, MD
Director
Center for Devices and Radiological Health
Food and Drug Administration

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